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25570	7590	07/30/2007		
ROBERTS, MLOTKOWSKI & HOBBS			EXAMINER	
P. O. BOX 10064			SRIVASTAVA, KAILASH C	
MCLEAN, VA 22102-8064				
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/853,635

Applicant(s)

OLSON, BENGT KRISTER

Examiner

Dr. Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 104-139 is/are pending in the application.
- 4a) Of the above claim(s) 105, 107, 116, 118, 119, 121-123, 128, 132 and 133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 104, 106, 108-115, 117, 120, 124-127, 129-131 & 134-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Your response, amendments and remarks filed 09 May 2007 in response to Office Action mailed 09 April 2007 are acknowledged and entered.
2. Response, amendments and remarks filed 30 November 2006 in response to Office Action mailed 30 July 2006 are also acknowledged and entered.

General Matters

3. The present Office Action jointly addresses the responses, amendments and remarks filed on 09 May 2007 and on 30 November 2006 respectively.
4. Note, the Supplemental Amendment filed 09 May 2007 clearly states, "This listing of claims will replace all prior versions and listings of claims in the application" (See Page 3, Lines 6-7). Accordingly, any and all rejections in the instant Office action are drawn to the set of Claims accompanying the amendment and response filed 09 May 2007.
5. Incorporation of application identifiers (e.g., U.S. Non-provisional Application Number, Filing Date for said application, Attorney Docket Number, Inventor's name, Art Unit USPTO, and Examiner's name) in the header of the each page of the amendment and responses filed 09 May 2007 and 30 November 2006 is greatly appreciated.
6. Also appreciated are applicant's representative's compliments regarding the telephone Interview summary. The applicant's representative went beyond the call of duty in making such gracious remarks.
7. For the record, the Office Action to which applicant has filed a response on 30 November 2006 was neither dated 30 July (See applicant's response filed 30 November 2006, Page 1, Line 19), nor mailed on said date. Said Office Action is dated 23 July 2006 (See Page 8, last line, Office Action dated 31 July 2006) and was mailed on 31 July 2006 (See Page 1, Line 16). Applicant please make appropriate correction to clear the record.
8. Please note that the Art Unit location of your application at the United States Patent and Trademark Office (i.e., USPTO) is changed. Your application has now been assigned to Art Unit

1657. To expedite the prosecution of the instant application and in correlating any papers for the instant application (i.e., 09/853,635) please ensure that all further correspondence regarding the instant application is directed to Art Unit 1657.

9. The assigned Examiner to your application at the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for this application (i.e., 09/853,635) all further correspondence regarding the instant application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

10. Claims 1-103 have been cancelled.
11. Claims 138-139 have been added.
12. Claims 105, 107, 116, 118-119, 121-123, 128, and 132-133 remain withdrawn.
13. Claims 114-115 and 129-130 have been amended.
14. Claims 104-139 are pending.
15. Claims 104, 106, 108-115, 117, 120, 124-127, 129-131 and 134-139 are examined on merits.

Restriction/Election

16. Applicant continues to traverse the Restriction requirement made in Office Action mailed 28 March 2006. Applicant's traversal is on the grounds:

- (i) that applicant's non-elected claims, "while patentably distinct " from the claims encompassed in Group I claims are related in subject matter to the claims that applicant has elected for further prosecution in the response filed 28 April 2006;
- (ii) "According to MPEP, when the claims can be searched and examined together without serious burden, even though the claims are drawn to independent or distinct inventions, the USPTO must examine the claims together on the merits";
- (iii) "To demonstrate the burden, the USPO must show that the groups have a separate classification, acquired a separate state in the art or searching would require different fields";

(iv)“Linking Claim 104, links Groups I-VII not just I-III and VII because components claimed in Claim 104 are also present in the inventions of Groups IV-VII”.

As is of record in the Office Action mailed 31 July 2006, Applicant’s above-stated arguments were not found persuasive because of the reasons of record in items 8-10 on pages 2-4 in Office Action mailed 28 March 2006, and those elucidated below:

Applicant admits on record that the invention of Group I, encompassing Claims 104, 106, 108-115, 117, 120, 124-127 and 129-131 is “distinct” than that Claimed in inventions of Groups II-VII. Moreover, in the Office Action mailed 28 March 2006, the Examiner has clearly pointed out the Classification (i.e., Class and subclass), state in the art and searching requirements for each of the inventive groups (See Page4, item 10, Paragraph 2). Furthermore, the burden lies not only in the search of literature, non-patent literature, U.S. and non-U.S. patents, but burden also lies in the examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Clearly different searches and issues are involved with each group. Moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

Applicant has the option to petition the Restriction requirement in Office Action mailed 28 March 2006 and Examiner’s decision to make said Restriction Requirement Final on the grounds (e.g., “Applicant admits on record that the invention of Group I, encompassing Claims 104, 106, 108-115, 117, 120, 124-127 and 129-131 is “distinct” than that Claimed in inventions of Groups II-VII”) stated in the Office Action mailed31 July 2006 (See Page 3, item 4, Lines 19-33).

Objections to Specification

17. In view of amendments and remarks filed 30 November 2006 and 09 May 2007, objection to specification in Office Action mailed 30 July 2006 is hereby withdrawn.

Claim Objections

18. Claim 104 has been objected to because it is not clear how one can make a distinction between the natural and synthetic components for each of the glycosaminoglycan and

polyphenolic, hydrophilic antioxidant, recited in said claim, wherein the natural sources for said components are: cartilage enzymatic hydrolysate and grape seed respectively.

In response to the above-cited objection in the Office Action mailed 31 July 2006 applicant's argument is, "a person of ordinary skill in the art would be readily able to differentiate between such components which are synthetic or obtained from a natural source because methods for differentiation of such components are known." Applicant has, however, not recited any known method for said differentiation, nor has the applicant given any reference source where said method is documented.

Applicant's arguments discussed *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Page 5, item 10 of the Office Action mailed 31 July 2006 and further because of the discussion presented above. Accordingly, the objection to Claim 104 in Office Action mailed 31 July 2006 is adhered to and maintained.

Claim Rejections - 35 U.S.C. §112

19. In view of amendments and remarks filed 09 May 2007 rejection to Claim 115 under 35 U.S.C. §112, 2nd Paragraph in Office Action mailed 30 July 2006 is hereby withdrawn.

20. In view of amendments and additions to the Claims in the response and amendment filed 09 May 2007 following are new rejections under 35 U.S.C. §112, second paragraph.

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §112, second paragraph that form the basis for the rejections under this section made in this Office action:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

22. Claims 114-115, 1129-130 and newly presented Claim 138 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In each of the Claims 114, 115, 129, 130 and 138 respectively, the limitation "grape seed extract" lacks sufficient antecedent basis because each of said claims directly, or indirectly depends from Claim 104. Claim 104 recites, "grape seed" (See item ii, Line 1).

- In each of the Claims 115 and 138 respectively, the limitation “50-200 mg of cartilage enzymatic hydrolysate” lacks sufficient antecedent basis because each of said claims directly, or indirectly depends from Claim 104. Claim 104 recites, “glycosaminoglycan found in cartilage enzymatic hydrolysate” (See item i, Line 1), not merely “cartilage enzymatic hydrolysate”.
- In each of the Claims 129-130 respectively, the limitation “wherein the cartilage enzyme hydrolysate “present in a weight/weight ratio” lacks sufficient antecedent basis because each of said claims directly, or indirectly depends from Claim 104. Claim 104 recites, glycosaminoglycan found in cartilage enzymatic hydrolysate” (See item i, Line 1), not merely “cartilage enzymatic hydrolysate”.

Appropriate correction(s) is required.

Claim Rejections Under 35 U.S.C. § 103(a)

23. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 104, 106, 108-115, 117, 120, 124-127, 129-131 and newly presented Claims 138-139 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Kosbab (WO 00/07607) in view of Bombardelli et al. (EP 0,6559,402) and Hersh (U.S. Patent 5,906,811).

In response to rejections to Claims 104, 106, 108-115, 117, 120, 124-127, 129-131 under 35 U.S.C. § 103 (a) cited *supra* in Office Action mailed 30 November 2006, applicant, citing a number of case laws argues that these references, alone or in combination do not establish *aprima faciae* case of obviousness to make the applicant's invention claimed in Claims 104, 106, 108-115, 117, 120, 124-127, 129-131 unpatentable and therefore do not render the instantly claimed invention unpatentable/obvious. Applicant further argues that instant application also discloses, “unexpected properties of the claimed invention because applicant demonstrates that the combination of cartilage extract (F), grape seed extract (G) and tomato extract (T) synergistically increases collagen synthesis compared to the individual compounds.

Applicant's claimed invention is drawn to a method to increase collagen synthesis or lessening the decrease in collagen synthesis via oral administration of a composition comprising one glycosaminoglycan from cartilage enzymatic hydrolysate, one polyphenolic, hydrophilic antioxidant present in grape seed and lycopene obtained from tomato extract. Applicant in arguments presented in the remarks filed 30 November 2006 and amendment filed 09 May 2007, however, repeatedly recites quantities of "cartilage enzymatic hydrolysate". Since invention is the subject matter defined by the claims, Applicant has to clearly state on the record the exact composition being orally administered in the claimed method to increase collagen synthesis in the dermis. Is it a glycosaminoglycan present in the cartilage enzymatic hydrolysate, or the cartilage enzymatic hydrolysate itself in combination with a polyphenolic, hydrophilic antioxidant present in grape seed and lycopene obtained from tomato extract that is being administered?

As stated at Page 5, item 12, Line 9 to Page 6, Line 23 of the Office action mailed 31 July 2006, Kosbab clearly teaches a method to enhance collagen production and maintenance thereof (i. e., the concentration of collagen does not decrease) in an individual via administering a composition comprising cartilage extract or chondroitin sulphate (i.e., a glycosaminoaglycan), antioxidant (i.e., carotenoids, e.g., beta carotene, and flavonoids) containing plant extracts and lycopene (See Kosbab reference, Page 24, Lines 10, 20-21 and 24-25). Bombardelli et al's teachings support Kosbab's because Bombardelli et al. teach an orally administered composition comprising lycopene, beta carotene and procyanidine oligomers from *Vitis vinifera* (See Bombardelli et al. reference, Page 6, Lines 47-53 and Page 7, Lines 1-4). Hersh teaches a method to orally administer a composition comprising acerola extract, beta carotene and proanthocyanidines from grape seed extract (See Hersh reference Column 18, Line 61 to Column 19, Line 7). Thus, motivation to combine the teachings from each of Kosbab, Bombardelli et al. and Hersh is in the references themselves as Kosbab and Hersh teach orally administering a composition comprising components that are claimed in the instantly claimed method and Bombardelli et al. reference substantiates the composition taught in Kosbab's teaching. Thus, Kosbab and Hersh teach a method to enhance/maintain collagen synthesis via orally administering to an individual in need thereof a composition comprising same components and according to the same steps as are claimed in the instant method invention. Newly presented Claims 138-139 depend from Claim 104 and are, therefore, rejected under 35 U.S.C. §103 (a) on the same grounds as discussed above.

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Note that although each of the Examiner-cited references by themselves may not teach every component in the same order or manner as claimed in the elected claims under prosecution in the instant application, these references are not relied upon exclusively but in combination. Moreover, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or Describe applicant's invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the claimed invention was made. Furthermore, the instantly claimed invention would have also been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose and also because of the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of each of the ingredients, *In re Sussman*, 1943 C.D. 518. It will also be *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T] he idea of combining them flows logically from their having been individually taught in the prior art." (*In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted)).

Applicant's arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Page 5, item 12, Line 9 to Page 6, Line 23 of the Office action mailed 31 July 2006 and further for the reasons explained in the preceding paragraph.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at Page 5, item 12, Line

9 to Page 6, Line 23 of the Office action mailed 31 July 2006 and for additional reasons as discussed *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

CONCLUSION

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


26. For the aforementioned reasons, no claims are allowed.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

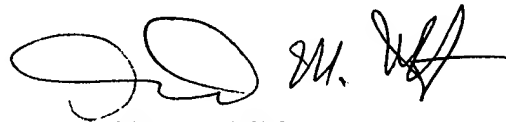
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system,

contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

23 July 2007


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT ~~128~~ 1657